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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/715,478	11/17/00	ALLISON	B 2196/1E500

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EXAMINER	
HUI, S	
ART UNIT	**PAPER NUMBER**
1617	4

DATE MAILED: 05/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/715,478	ALLISON ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Claim Objections

Claim 1 objected to because of the following informalities: parenthetical expression e.g. "(PS)" is improper. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the porphyrin derivatives that are disclosed in specification page 30, line 5 – page 31, line 15 and photosensitizers at page 17, line 18 to page 35, line 15, does not reasonably provide enablement for other porphyrin derivatives or other photosensitizers. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There is no adequate direction provided by the applicant as to how to select any other suitable porphyrin derivatives or photosensitizers to be used in the invention to treat, prevent, inhibit or reduce restenosis or intimal hyperplasia in adjunct with angioplasty. Furthermore, the instant specification does not provide any working examples to show how any other porphyrin derivatives or photosensitizers besides the photosensitizers that are disclosed in specification page 17, line 18 to page 35, line 15,

may be used successfully in the invention to treat, prevent, inhibit or reduce restenosis or intimal hyperplasia in adjunct with angioplasty.

Moreover, it is known in the art that different compounds may have different potency and activity because of the structural and conformational differences in the compounds. Therefore a different porphyrin derivatives other than the porphyrin derivatives that are disclosed in specification page 30, line 5 – page 31, line 15, may be reasonably expected to yield a different result. For the same reason, different photosensitizer compounds other than the photosensitizer compounds that are disclosed in specification page 17, line 18 to page 35, line 15, may be reasonably expected to yield a different result in restenosis or intimal hyperplasia. Due to this unpredictability, it would prevent the skilled artisan from determining compounds which may be termed an "porphyrin derivative" or "photosensitizers" to retain the desired function of the instant invention to treat, prevent, inhibit or reduce restenosis or intimal hyperplasia in adjunct with angioplasty without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 contains the trademark/trade names BPD-MA and A-EA6 (See claim 8, line 1). Where a trademark or trade name is used in a claim as a limitation to identify or

describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe several structurally different green porphyrin compounds and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vincent et al. (US Patent 5,422,362) in view of Adili et al. (Lasers in Surgery and Medicine 1998, 23:263-273).

Vincent et al. teaches a method to prevent or inhibit intimal hyperplasia in adjunct with angioplasty in a subject with the administration of BPD-MA concurrent with or within 6 hours of the injury and following the angioplasty. Vincent et al. also teaches that the BPD-MA is administered to the angioplasty-injured site (See abstract; also

col.10, example 1; and claims 1-22). Vincent et al. also teaches that the method is applicable to various angioplasty procedures broadly including any procedure which involves traumatic manipulation of the vasculature (See col. 3, line 62 – col. 4, line 4).

Vincent et al. does not expressly teach that radiation is applied in the method. Vincent et al. does not expressly teach the time to administer BPD-MA to be within 10 or 15 minutes of the angioplasty procedure.

Adili et al. teaches the use of BPD-MA in a method to inhibit Intimal hyperplasia with the use of radiation within 15 minutes of the administration of BPD-MA (See page 265, col.1 last para. to col.2, second para.).

It would have been obvious for one of ordinary skill in the art at the time the invention was made to apply radiation onto BPD-MA in a method of inhibiting intimal hyperplasia in adjunct with angioplasty. It would have been obvious for one of ordinary skill in the art at the time the invention was made to administer BPD-MA to be within 10 or 15 minutes of the angioplasty procedure.

One of ordinary skill in the art would have been motivated to apply radiation onto BPD-MA in a method of inhibitinging, preventing or reducing intimal hyperplasia in adjunct with angioplasty because BPD-MA is known to be useful in a method of inhibiting intimal hyperplasia. Therefore, the irridiation of BPD-MA in the adjunct method of inhibiting or preventing intimal hyperplasia in Vincent et al. would have been reasonably expected to be useful in the instant intimal hyperplasia inhibition method.

Optimization of result effect parameters (dosing regimens e.g., frequency, and timing of radiation) is obvious as being within the skill of the artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Monday to Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
May 21, 2001

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